

REMARKS**FORMAL MATTERS**

Claims 1 and 10 have been amended to include the phrase ‘and said composition lacking a second population of particles comprising a water-soluble drug.’ Support for these amendments may be found throughout the specification as originally filed, including Example 1 of the present application.

Claims 3-5, 7-9 and 11 are not amended.

No new matter is added.

REJECTIONS UNDER § 112, SECOND PARAGRAPH

The Examiner has maintained the rejection of the claims alleging that the description contains statements that indicate that a capsule is required for the present invention and cites the Example on page 4 of the present application as evidence that such a capsule is required. Applicant points out that nowhere in the Example is it stated that the capsule is a required or essential part of the invention. A statement of essentiality would be required for such a rejection under §112, second paragraph. Page 2 at lines 20-26 of the present application makes it clear that such a capsule is not required. This portion of the application states that particles can be made of a single type that release a drug in two spikes and that the present invention is a pharmaceutical composition comprising such particles. A person of skill in the art would understand that it may be convenient to contain a particular quantity of such particles in a vehicle such as a capsule or a folded piece of paper, but that such a vehicle is not required. The fact that a capsule was used in Example 1 of the application is not relevant to the essentiality, or lack thereof, of a capsule.

The Examiner also advises that the claims are read in light of the specification, but that limitations from the specification are not read into the claims. Applicant agrees and notes that there are no limitations from the specification that the Applicant intends to be read into the claims. Indeed, simply because there is a statement in the specification does not mean that such a statement is to be read into the claims. The Examiner states that “Applicant’s lone Example depicting a final encapsulated product discusses the use of an additional and seemingly requisite

element of the invention in the capsule” [emphasis added]. This statement makes it clear that the Examiner acknowledges that there is no clear statement in the specification indicating essentiality of a capsule, otherwise it would not be seemingly, it would be clear. The Examiner then goes on to state “it is thus interpreted by the Examiner that the recited invention omits a structurally essential element from said invention, absent evidence to the contrary” [emphasis added]. It is clear that interpretation on the part of the Examiner was used and such an interpretation is inappropriate for such a rejection under 35 U.S.C. § 112.

MPEP § 2172.01 (as cited by the Examiner) in pertinent part states

In addition, a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention.
[Emphasis added]

There is no evidence that the capsule is an essential element and the evidence to the contrary which the Examiner alleges is required may be found on page 2 of the application at lines 20 to 26 as well as the lack of a clear statement by the applicant in the specification identifying that the capsule is required. The Examiner is respectfully requested to withdraw the rejection.

REJECTIONS UNDER § 103(A)

The Examiner maintained the rejection of claims 1, 3-5 and 7-11. Claims 1 and 10 (the only independent claims) are amended to include the phrase “and said composition lacking a second population of particles comprising a water-soluble drug”. This phrase makes it clear that the compositions of the present invention, which may optionally comprise other components such as capsules or not, cannot comprise a second population of particles comprising a water-soluble drug. It is believed that the claims, as amended, overcome the Examiner’s concerns.

CONCLUSION

The pending claims are believed to satisfy all of the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided below.

No fees beyond those submitted herewith are believed to be due in connection with this communication. However, the Commissioner is authorized to charge any underpayment of fees associated with this communication under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-4648, order number **PT2099001**.

Respectfully submitted,
APOTEX INC.

Date: September 28, 2009

By: 

Graham J. K. McKinnon
Registration No. 56,687

APOTEX INC.
150 Signet Drive
Toronto, Ontario M9L 1T9
Telephone: (416) 749-9300
Facsimile: (416) 401-3849